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| 10/718,492 | 11/20/2003 | Christopher C. Toly | SIMU0004 | 8227 |
| 25268 | 7590 | 03/10/2006 | EXAMINER | |
| LAW OFFICES OF RONALD M ANDERSON 600 108TH AVE, NE SUITE 507 BELLEVUE, WA 98004 | | | CHENG, JOE H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3715 | |

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,492

Applicant(s)

TOLY, CHRISTOPHER C.

Examiner

Joe H. Cheng

Art Unit

3715

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 10-14, 17-19, 36, 42, 46 and 62-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 15, 16, 20-35, 37-41, 43-45, 47-61 and 74-87 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-41, 43-45, 47-61 and 74-87, drawn to the physiological training and evaluation simulator system and method for training and testing personal, classified in class 434, subclass 262.
- II. Claims 42, 46, 62-73, drawn to the method for making a conductive elastomer-based evaluation circuit, classified in class 73, subclass 716.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are prima facie independent and distinct inventions due to their recitations of distinct and specific structures. Invention I is directed to the structural elements of the physiological training and evaluation simulator system and method for training and testing personal. Invention II is directed to the method for making a conductive elastomer-based evaluation circuit. Because these inventions are distinct for the reasons given above and has acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. It is noted that if applicant elected Invention I, applicant is required to elect one of the species, because this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Art Unit: 3715

The species are as follows:

Species #1 : Fig. 11A;

Species #2 : Fig. 11B;

Species #3 : Fig. 11C;

Species #4 : temperature sensor;

Species #5 : chemical sensor.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Specie #1 - claims 4, 17, 36, 48, 56 and 60;

Specie #2 - claims 7, 48, 56 and 60;

Specie #3 - claims 11, 48, 56 and 60;

Specie #4 - claim 18;

Specie #5 - claim 19.

5. The following claim(s) are generic: 1, 2, 16, 35, 45, 55 and 57.

Art Unit: 3715

6. During a telephone conversation with Mr. Michael C. King (applicant's attorney) on March 3, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-41, 43-45, 47-61 and 74-87 and Species #2, claims 7, 16, 48, 56 and 60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-6, 10-14, 17-19, 36, 42, 46 and 62-73 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species.

Specification

7. The disclosure is objected to because of the following informalities: The term "This application is a continuation-in-part of a copending application, Ser. No. 09/695,380, filed on Oct. 23, 2000, the benefit of the filing date of which is hereby claimed under 35 U.S.C. § 120." on the first paragraph of page one should be recited as --This application is a continuation-in-part of U.S. Application Serial No. 09/695,380, filed on Oct. 23, 2000, now U.S. Pat. No. 6,780,016 B1, the content is incorporated herein by reference.-- to clarify the status. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 7-9, 15, 16, 20-35, 37-41, 43-45, 47-61, 75, 78, 82-84 and 87 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that

Art Unit: 3715

the claimed structural elements can not perform the function of training and testing/evaluating of the personnel (as per claims 1-3, 7-9, 15, 16, 20-35, 37-40, 42-57, 60) to properly perform the simulated medical procedure as claimed. In addition, it is not understood as to what is the meaning of "to determine a physiological response for the medical training-simulate *to emulate*" (as per claim 78). Further, the references for "a meter" (as per claim 23), "a servo" (as per claims 33 and 84) and "a pump" (as per claims 33 and 83), "a neural network" (as per claims 37 and 87) and "human nervous system" (as per claim 87) are unclear. Furthermore, the antecedent basis for "the processor" (as per claim 82) has not been clearly set forth. Finally, claims 41, 58, 59 and 61 are rejected for incorporating the above errors from their respective parent claims by dependency.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 3715

11. Claims 1-3, 7-9, 15, 16, 20-22, 31, 32, 34, 35, 45, 47-54, 56-61, 74-82 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (U.S. Pat. No. 4,907,973) in view of D'Antonio et al (U.S. Pat. No. 5,510,605). The broadly claimed structure can be interpreted as the expert system and simulator for modeling realistic internal environment and performance of Hon. Figs. 1-17 of Hon broadly discloses the physiological training and evaluation simulator and method suitable for training and testing personnel comprising the simulated physiological structure (1b) comprising a simulated organ (51), more than one of the evaluation circuit (i.e. sensor, 97a-97n, 98a-98n, 320) for providing data related to a simulated medical procedure being performed by the simulated physiological structure and to provide feedback related to the simulated medical procedure when a specific portion of the simulated physiological structure is manipulated, e.g. when at least a portion of the simulated physiological structure is touch or when an instrument is in proximity to at least a portion of the simulated physiological structure (see Figs. 1-3, 5-9 and column 4, lines 27-53 and from column 5, line 20 to column 7, line 49), the physiological control element (345) for producing the simulated physiological response to the processor (124, 226, 355), and the processor processing the data to determine the medical training simulator to be simulate, to determine whether the simulated medical procedure to be performed on the simulated physiological structure is properly performed, to determine the score rating a quality of the simulated procedure by comparing the score for the simulated procedure to at least one score from a previous simulated procedure (from column 9, line 52 to column 12, line and from column 13, line 25 to column 15, line 5), and to provide audio and visual feedback regarding the performance of the procedure, e.g. the light indicator (2) based on the rate/score of the learning. It is noted that the teaching of Hon does not specifically disclose the conductive

Art Unit: 3715

elastomer-based evaluation circuit (as per claims 1, 2, 45, 55, 57, 74 and 79) and to provide signal when is touch (as per claims 7, 48, 56, 60) as required. However, the teaching of D'Antonio et al broadly discloses that such features of the conductive elastomer-based evaluation circuit having the capacitance sensitive switch or the resistance sensitive switch (see from column 5, line 61 to column 6, line 28) to provide signal when is touch are old and well known. Hence, it would have been obvious to one of ordinary skill in the art to modify the simulator and method of Hon with the features of the conductive elastomer-based evaluation circuit for providing signal when is touch as taught by D'Antonio et al as both Hon and D'Antonio et al are directed to the physiological training and evaluation simulator and method, so as to providing the training and testing of the medical skill to the person who perform the medical procedure.

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (U.S. Pat. No. 4,907,973) in view of D'Antonio et al (U.S. Pat. No. 5,510,605) and further in view of Pugh (U.S. Pat. No. 6,428,323 B1). It is noted that the teachings of Hon and D'Antonio et al do not explicitly disclose the meter as required. However, the teaching of Pugh broadly discloses that such feature of the meter (49, 50, 52, 54) providing feedback regarding the performance of the procedure. Hence, it would have been obvious to one of ordinary skill in the art to modify the simulator and method of Hon and D'Antonio et al with the feature of the meter as taught by Pugh as both Hon, D'Antonio et al and Pugh are directed to the physiological training and evaluation simulator and method, so as to provide the feedback regarding the performance of the procedure.

Art Unit: 3715

13. Claims 24, 25, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (U.S. Pat. No. 4,907,973) in view of D'Antonio et al (U.S. Pat. No. 5,510,605) and further in view of Niiranen et al (U.S. Pat. No. 2,871,579). It is noted that the teachings of Hon and D'Antonio et al do not specifically disclose the simulated human tissue structure (as per claim 24) having at least one simulated membranous layer and a second simulated sub-membranous layer (as per claims 25 and 44) as required. However, the teaching of Niiranen et al broadly discloses that such features of the simulated human tissue structure (see Fig. 4) having at least one simulated membranous layer (19) and a second simulated sub-membranous layer (15) are old and well known. Hence, it would have been obvious to one of ordinary skill in the art to modify the simulator and method of Hon and D'Antonio et al with the features of the structure of the simulated human tissue as taught by Niiranen et al as both Hon, D'Antonio et al and Niiranen et al are directed to the physiological training and evaluation simulator and method, so as to provide the realistic simulated medical procedure.

14. Claims 26-28, 55 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (U.S. Pat. No. 4,907,973) in view of D'Antonio et al (U.S. Pat. No. 5,510,605) and further in view of Talmage, Jr. et al (U.S. Pat. No. 4,687,885). It is noted that the teachings of Hon and D'Antonio et al do not specifically disclose that the conductive elastomer-based evaluation circuit is implemented in three dimension (as per claim 26) as a three-dimensional grid (as per claims 27, 28 and 86), or comprising a conductor encapsulated by the first and second elastomeric layers (as per claim 55) as required. However, the teaching of Talmage, Jr. et al broadly discloses that such features of the conductive elastomer-based evaluation circuit is

Art Unit: 3715

implemented in three dimension as a three-dimensional grid, or comprising a conductor encapsulated by the first and second elastomeric layers (see from column 4, line 40 to column 5, line 41 and from column 6, line 67 to column 8, line 15) are old and well known. Hence, it would have been obvious to one of ordinary skill in the art to modify the simulator and method of Hon and D'Antonio et al with the features of the conductive elastomer-based evaluation circuit is implemented in three dimension as a three-dimensional grid, or comprising a conductor encapsulated by the first and second elastomeric layers as taught by Talmage, Jr. et al as both Hon, D'Antonio et al and Talmage, Jr. et al are directed to the physiological training and evaluation simulator and method, so as to provide the three-dimensional grid of the evaluation circuit.

15. Claims 29, 30, 33, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (U.S. Pat. No. 4,907,973) in view of D'Antonio et al (U.S. Pat. No. 5,510,605) and further in view of Szinicz (U.S. Pat. No. 5,425,644). It is noted that the teachings of Hon and D'Antonio et al do not specifically disclose that the plurality of integral fluid channels (as per claim 29) and the wall of at least some of the fluid channels (as per claim 30), and the servo (as per claims 33 and 84) or the pump (as per claim 33 and 83) as required. However, the teaching of Szinicz broadly discloses that such features of the plurality of integral fluid channels (24a, 24b, 32a, 32b) and the wall of at least some of the fluid channels (30), and the servo or the pump (12) are old and well known. Hence, it would have been obvious to one of ordinary skill in the art to modify the simulator and method of Hon and D'Antonio et al with the features of the structure of the wall of at least some of the fluid channels with the servo or the pump as taught

Art Unit: 3715

by Szinicz as both Hon, D'Antonio et al and Szinicz are directed to the physiological training and evaluation simulator and method, so as to provide the realistic feeling of the simulated medical procedure.

16. Claims 37-41 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (U.S. Pat. No. 4,907,973) in view of D'Antonio et al (U.S. Pat. No. 5,510,605) and further in view of Leight et al (U.S. Pat. No. 6,675,757 B1). It is noted that the teachings of Hon and D'Antonio et al do not specifically disclose that the neural network (as per claim 37 and 87), the simulated joint (as per claim 38) and the simulated bone (as per claim 40) as required. However, the teaching of Leight et al broadly discloses that such features of the neural network the simulated joint, and the simulated bone (column 19, lines 27-33 and column 20, lines 1-24). Hence, it would have been obvious to one of ordinary skill in the art to modify the simulator and method of Hon and D'Antonio et al with the features of the neural network the simulated joint, and the simulated bone as taught by Leight et al as both Hon, D'Antonio et al and Leight et al are directed to the physiological training and evaluation simulator and method, so as to provide the realistic simulation for the simulated medical procedure.

Conclusion

17. Applicant is informed that the U.S. Pat. No. 5,205,286 and 5,320,537 have been crossed out by the Examiner are the duplicate of the same references cited in the Information Disclosure Statement (IDS) filed on March 3, 2004, and January 17, 2006. Moreover, the French Pat. No. FR 2 691 826 A1 and all the publication, which are crossed out by the Examiner, cited on the

Art Unit: 3715

IDS filed on January 17, 2006 have not been considered by the Examiner, because CFR § 1.98 requirement is not met, specifically, the legible copy of the publication is missing. Further, the prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tajima et al (U.S. Pat. No. 5,855,553) teaches the remote surgery support system and method for producing a presentation of realism control data generated by realism control data generating means from the image data obtained from work environment data detecting means and measurement data processing means and from force and proximity data. While viewing the presentation, the surgery operator inputs actions through action command inputting means and diseased tissue manipulating means executes a procedure on diseased part. Thereby a plurality of surgical operators can perform a surgical operation while viewing the realism control data and sensing the manipulating force of other surgical operators and the force reflection from the diseased part. Hon (U.S. Pat. No. 6,074,213) discloses the simulator for training medical teams, the members of which are located in different places, or stations, as they train together using the apparatus in coordinated fashion in relation to a numerical data, or virtual, non-physical model without input from a live instructor. Each remote station provides a differentiated input with a plurality of differentiated devices, and receives differentiated feedback from the model to each individual station in representations which are visual, tactile, aural, and/or olfactory in their display, depending on the feedback required by each individual station. Bailey (U.S. Pub. No. 2001/0055748 A1) discloses the system for producing highly realistic, real-time simulated operating conditions for interactive training of persons to perform minimally invasive surgical procedure involving implements that are inserted and manipulated through small incisions in the patient. Anderson et al (U.S. Pub. No. 2002/0168618 A1) teaches the system and method for

Art Unit: 3715

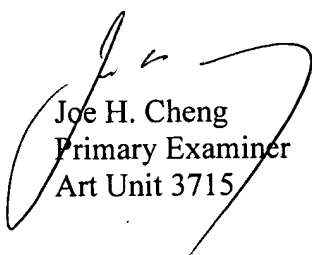
computer simulation of image-guided diagnostic and therapeutic procedures such as vascular catheterization, angioplasty, stent, coil and graft placement, embolotherapy and drug infusion therapy.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joe H. Cheng whose telephone number is (571)272-4433. The examiner can normally be reached on Tue. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Monica S. Carter can be reached on (571)272-4475. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joe H. Cheng
March 2, 2006


Joe H. Cheng
Primary Examiner
Art Unit 3715